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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC., and ALLERGAN INDUSTRIE, SAS,

Plaintiffs,

v.

MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS INTERNATIONAL, INC.

Defendants.

Case No. 8:13-cv-01436 AG (JPRx)

DEFENDANTS' OPENING CLAIM CONSTRUCTION BRIEF

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Defendants Medicis Aesthetics, Inc., Medicis Pharmaceutical Corp., Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals International, and Valeant Pharmaceuticals International, Inc. (collectively, "Defendants") respectfully submit this opening brief on the construction of terms in Plaintiff Allergan's U.S. Patent Nos. 8,450,475 (the "'475 Patent") and 8,357,795 (the "'795 Patent").

Relevant portions of the patents' prosecution histories are exhibits to the Declaration of William F. Cavanaugh ("Cavanaugh Declaration" or "Cavanaugh Decl.").

I. PRELIMINARY STATEMENT

"Patent scope should be coextensive with what the inventor invented as evidenced by what is disclosed in the patent specification." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 815 (Fed. Cir. 2007). In keeping with this tenet, Defendants' proposed claim constructions align with the claim and patent specifications, and properly define the scope of the claims under governing law. Conversely, through claim construction and in an effort to reach Defendants' products, plaintiffs seek to broaden the scope of the patents-in-suit well beyond what was invented and into what the patentees disclaimed they had invented because it was already in the prior art. This patent infringement case involves dermal fillers used as cosmetic treatments to reduce facial wrinkles, depressions, and other effects of aging by augmenting or restoring the fullness of soft tissues underneath the skin. The fillers at issue in this case are those comprised of hyaluronic acid, a crosslinker, and the anesthetic lidocaine. As discussed below, these dermal filler compositions are comprised of both an "uncrosslinked" form of HA, which is a water-soluble liquid, and a "crosslinked" form of HA that is a water-insoluble gel. Plaintiffs seek to blur the differences between the two. In addition, the patentees only asserted that they invented a mixture of the two but only when the uncrossliked HA is added back into the gel form of HA, creating a mixture with specific ranges of the degree of crosslinking. All the foregoing is ignored in Plaintiffs' proposed claim constructions in an effort to create a theory of infringement because Defendants' products do not add back uncrosslinked HA or contain the specified ranges of the degree of crosslinking.

A. History/State of the Art

In the United States, dermal fillers are considered to be medical device implants and must be approved for use by the U.S. Food and Drug Administration ("FDA"). They became available in the United States as early as the 1980s, in the form of collagen-based fillers such as Zyderm®/Zyplast® and Fibrel®. '795 Patent, 1:42-45; Cavanaugh Decl, Ex. 1 ("*Tezel*") at 35. But collagen had its drawbacks when used in dermal fillers. It did not last particularly long and required immunogenic testing before the patient received a collagen injection. '795 Patent at 45-59.

Researchers then investigated hyaluronic acid ("HA") as a collagen replacement. HA is a naturally-occurring glycosaminoglycan frequently found in human connective, epithelial, and neural tissues. *Id.* at 1:66 – 2:2. One benefit of HA is that it lacks the allergy-related complications of collagen. *Id.* at 2:2-4. But HA, in its native form, has one of the same drawbacks as collagen – HA does not remain in the human tissue into which it is applied for long before it disperses and is absorbed into the body. *Tezel* at 36.

To solve this problem, researchers chemically modified HA by covalently bonding the compound to various crosslinking agents, including 1,4-butanediol diglycidyl ether ("BDDE") and divinylsulfone ("DVS"). '795 Patent, 2:50-58; Cavanaugh Decl., Ex. 2 ("*Calias*"), at 1:11-14; *Tezel* at 39. As a result, the "crosslinked" HA becomes a gel. *Tezel* at 37. As more crosslinker is added, the number of bonds formed between HA chains increases. This results in a more stable, but less flexible, gel. The "degree of crosslinking," the ratio of the weight of the crosslinking agent to the weight of HA in a portion of crosslinked HA, is used to estimate the relative stability and flexibility of the gel. For example, an HA gel with a high degree of crosslinking is generally more stable but less flexible than an HA gel with a low degree of crosslinking.

There was, however, a new drawback to using crosslinked HA as a dermal filler. Because crosslinked HA is a substantially solid gel, it cannot easily pass through a needle to be injected. Therefore, after the gel forms, it must be broken apart into particles that can be injected. In addition, to make these particles of crosslinked HA gel easier to inject, HA in its uncrosslinked form

(*i.e.*, "uncrosslinked HA" or "free HA") was added. *Id.* at 39. The use of a mix of crosslinked and uncrosslinked HA in these fillers not only improved the stability of the composition, it also reduced the extrusion force necessary to inject the filler into a patient. '475 Patent, 2:7-19; *Tezel* at 39.

In December 2003, the first HA dermal filler was approved by the FDA. This filler was Restylane®. '475 Patent, 1:63-64; *Tezel* at 35. "[T]his was rapidly followed by the development of other HA-based fillers." '475 Patent, 1:64-65. Before August 2008, "methods of preparing HA-based soft tissue fillers including both crosslinked and free HA [were] well known." *Id.* at 2:18-19. These products included Restylane®, Juvederm® Ultra (J24HV) and Juvederm® Ultra Plus (J30HV), which all utilize the crosslinker BDDE. *Tezel* at 35.

Practitioners also recognized that injecting a dermal filler would be painful. As a result, practitioners often combined anesthetics such as lidocaine with fillers, such as Restylane® and Juvederm® products. '475 Patent, 2:20-22. Manufacturers began to incorporate lidocaine into their HA dermal fillers during the production process. For example, products such as Puragen® Plus and Prevelle® Silk, containing lidocaine and a combination of crosslinked and uncrosslinked HA, had been approved and reported on prior to August 2008. The two allegedly infringing products, Restylane-L® and Perlane-L®, and the three products sold by Plaintiffs, Juvederm® Voluma XC, Juvederm® Ultra XC, and Juvederm® Ultra Plus XC contain lidocaine. Juvederm Voluma XC was first approved in 2013, while the other products were first approved in 2010.

B. Patents-at-Issue[1]

The '475 Patent and '795 Patent are entitled "Hyaluronic acid-based gels including lidocaine." Both patents claim various compositions comprising (1) HA bound to a crosslinking agent and (2) lidocaine. The '475 Patent is limited to the use of BDDE as a crosslinking agent. They claim a priority date of August 4, 2008, the filing date of U.S. Prov. App. No. 61/085,956.

[1] Defendants assert that the prior art invalidates the patents-in-suit and will present these arguments at the appropriate time.

Plaintiffs assert that Defendants infringe claims of the '475 and '795 Patents by importing into and offering for sale within the United States both Restylane-L® and Perlane-L®.

i. The '795 Patent

The '795 Patent issued on January 22, 2013, claiming soft tissue filler compositions comprised of HA modified by a crosslinking agent to create crosslinked HA, and an anesthetic such as lidocaine. '795 Patent, 2:36-41; Claim 1. The '795 Patent provides for the use of multiple crosslinking agents. *Id.* at 2:50-58. The resulting composition is sterilized. *Id.* at 2:45-47.

The patent asserts that, previously, incorporating lidocaine into the manufacturing process for an HA dermal filler would cause the composition to become "prone to partial or almost complete degradation prior to injection, particularly during high temperature sterilization steps and/or when placed in storage for any significant length of time." *Id.* at 2:23-27. The patent also asserts that, unlike the prior art, the claimed compositions of crosslinked HA and lidocaine would remain stable – as defined by the Patent – for an extended period of time. *Id.* at 2:42-48.

ii. The '475 Patent

The '475 Patent issued on May 28, 2013, claiming soft tissue filler compositions comprised of a mixture of "free" or "uncrosslinked" HA, HA modified by a crosslinking agent to create crosslinked HA, and an anesthetic such as lidocaine. '475 Patent, 2:36-41. The '475 Patent is limited in its claims to crosslinking with 1,4-butanediol diglycidyl ether ("BDDE"). *See, e.g., id.* at Claims 1, 18, and 34. The resulting composition is sterilized. *Id.* at 2:45-47. The specification of the '475 Patent is substantially identical to that of the '795 Patent, with the exception that Example 4 of the ‘795 Patent is omitted in the ‘475 Patent.

II. THE LAW ON CLAIM CONSTRUCTION

Claim construction is a question of law for the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-90 (1996).

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude'." *Phillips v. AWH Corp.*, 415 F.3d

1303, 1312 (Fed. Cir. 2005) (en banc). Claim construction favors the meaning that "'most naturally aligns with the patent's description of the invention.'" *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societá per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)). "[T]he focus in claim construction is on 'the meaning of claim terms within the patent,' and not on the abstract meaning of words." *Reflex Packaging Inc. v. Lenovo (United States), Inc.*, No. 5:10-CV-01002-EJD, 2012 U.S. Dist. LEXIS 64594, at *20 (N.D. Cal. May 8, 2012) (quoting *Phillips*, 415 F.3d at 1321). But claims are not read in isolation. A court should construe a claim by looking at the evidence "intrinsic" to the patent, which means considering "the words of the claims themselves, the remainder of the specification, [and] the prosecution history." *Phillips*, 415 F.3d at 1314. The prosecution history is the "complete record of the proceedings before the PTO and includes the prior art listed during the examination of the patent." *Id.* at 1317. Often, the meaning of each claim is clear.

"[C]laims 'must be read in view of the specification, of which they are a part.'" *Phillips*, 415 F.3d at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*)). "[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The context in which a term is used in the asserted claim can be highly instructive," and "[often] provides a firm basis for construing the term." *Phillips*, 415 F.3d at 1314.

Although courts will often give terms their "ordinary and customary" meaning, a patentee may act as his or her own lexicographer by defining a claim term in the patent. *Vitronics*, 90 F.3d at 1582; *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001). Where the "patent expresses an intention to impart a novel meaning to claim terms," *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302 (Fed. Cir. 2003), that definition "controls the meaning of [the claim term], regardless of any potential conflict with the term's ordinary meaning ...." *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 (Fed. Cir. 2003). Thus, a claim term should not be given its "plain and ordinary meaning" where "the patentee demonstrated an intent to

deviate from the ordinary and accustomed meaning of a claim term by redefining the term ...." *SunRace*, 336 F.3d at 1304. These changes to a term's definition can be found not only in the patent itself, but also the prosecution history, which can "provide[ ] evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317; *Vitronics*, 90 F.3d at 1582-83. The prosecution history is intrinsic evidence and should be considered in exactly the same way as the text of the patent is considered.

In some instances the meaning of a claim remains unclear or ambiguous even after the intrinsic evidence is considered. In such instances, the court can look at evidence extrinsic to the patent record in order to resolve these questions. Extrinsic evidence is evidence beyond the patent and its prosecution history, including "expert and inventor testimony, dictionaries, and learned treatises." *See id.* at 1317-18. While extrinsic evidence is a secondary tool of claim interpretation, it can useful for determining the "true meaning of language used in the patent claims" when the meaning is otherwise unclear. *Phillips*, 415 F.3d at 1318 (citing *Markman*, 52 F.3d at 980).

III. THE DISPUTED CLAIM CONSTRUCTION ISSUES

Defendants' proposed constructions are consistent with the entirety of the intrinsic evidence – the claims, specification, and prosecution history – and relevant extrinsic evidence. Plaintiffs, in an attempt to narrow the scope of the asserted claims to avoid prior art or to broaden the scope of the asserted claims to encompass Defendants' products, propose constructions that do not comport with the specifications of the '475 and '795 patents or with how the claims were understood by both the inventor and the patent examiner during prosecution of the patents-in-suit before the U.S. Patent and Trademark Office ("USPTO"). Seven claim terms are disputed in whole or in part.

A. Claim Construction for the '475 Patent

1. Claims 1, 18, 27, 31, and 34: "stable"

Claim term	Plaintiffs' construction	Defendants' construction
Stable	resists chemical and physical decomposition	a sterile composition that maintains one of the following aspects: transparent appearance, pH, extrusion force and/or rheological characteristics, hyaluronic acid (HA) concentration, sterility, osmolarity, and lidocaine concentration, after being stored at about 25C for about two months.

Defendants' proposed construction is a direct quote of the definition given by the patentee in the specification of the '475 Patent. In the section of the specification entitled "DEFINITIONS" (4:34), "autoclave stable" is defined as a "product or composition resistant to degradation such that [it] maintains at least one, and preferably all, of the following aspects after effective autoclave sterilization: transparent appearance, pH, extrusion force and/or rheological characteristics, hyaluronic acid (HA) concentration, sterility, osmolarity, and lidocaine concentration." 4:41-48.[2] This definition is then repeated a second time in a discussion of the characteristics of a "stable" composition. 5:39-44. These specific characteristics are measured in the listed stability tests in Table 2. 14:1-24. The patent goes on to describe, further, the period of time in which these characteristics of stability are to be measured – "a period of at least about two months" during which the composition is kept at ambient "temperatures of at least about 25º C." 8:6-10. Confirming that the patentee was attempting to describe the claimed invention, and not just a specific embodiment, the specification later describes a narrower "specific embodiment [where] the compositions are stable at a temperature up to about 45 º C." 8:10-12.

Plaintiffs ask this Court to ignore the patentee's own definition and instead construe the term "stable" more broadly and generically as simply something that "resists chemical and physical decomposition." However, any ordinary meaning of "stable" does not control here because

[2] The portion of the construction referring to a "sterile composition" is a necessary condition based upon the patent's definition of "stable." For a product to be stable by maintaining sterility, it must be sterile initially.

the inventor chose to act as his own lexicographer. *Vitronics*, 90 F.3d at 1582; *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001). Where the "patent expresses an intention to impart a novel meaning to claim terms," *SunRace Roots Enter. Co.*, 336 F.3d at 1302, that definition "controls the meaning of [the claim term], regardless of any potential conflict with the term's ordinary meaning ...." *3M Innovative Props. Co.*, 350 F.3d at 1374.

Moreover, the construction proposed by Plaintiffs does not appear anywhere in the '475 Patent. In fact, the words "chemical," "physical," and "decomposition" do not appear in the claims or specification at all. Defendants' proposed construction should be adopted.

2. Claim 1, 31, 34: "HA crosslinked with 1,4-butanediol diglycidyl ether (BDDE)"/ Claim 18: "hyaluronic acid (HA) component crosslinked with 1,4-butanediol diglycidyl ether (BDDE)" / Claim 27: "(BDDE)-crosslinked hyaluronic acid"

Claim term	Plaintiffs' construction	Defendants' construction
HA crosslinked with 1,4-butanediol diglycidyl ether (BDDE) / hyaluronic acid (HA) component crosslinked with 1,4-butanediol diglycidyl ether (BDDE) / (BDDE)-crosslinked hyaluronic acid	HA that forms a macromolecular structure resulting from chemical linking of HA by BDDE	HA that has been covalently modified with BDDE to form a macromolecular structure that is water-insoluble, such that the degree of crosslinking is at least about 2% and is up to about 20%. "Degree of crosslinking" as used herein has the same construction as agreed by the parties.

The above claims include multiple claim terms describing HA crosslinked to the crosslinking agent BDDE ("crosslinked HA"). The parties have agreed the three variations identified above should be construed the same way. Dkt. No. 52.

Both parties accept that HA and BDDE form a macromolecular structure, but disagree in three other respects.

"Covalently Modified" vs. "Chemical Linking"

Plaintiffs' construction refers only to "chemical linking" of HA by BDDE while Defendants' construction specifies that the HA has been "covalently modified." Defendants do not understand Plaintiffs to be challenging the fact that the bond between HA and BDDE is a covalent bond that modifies the HA. *See* Cavanaugh Decl, Ex. 3 ("*Reinmuller II*"), at 2:9-16 ("Further suitable reagents for the covalent crosslinkage of hyaluronic acid are . . . ethylene glycol diglycidyl ether or 1,4-butanediol diglycidyl ether, divinyl sulfone, [and other reagents]") (emphasis added); *Calias*, 2:26-30 (referencing an earlier patent which "describe[d] the preparation of cross-linked polysaccharides, including HA, wherein the cross-linking reaction occurs as a result of covalent bonds formed between carboxyl groups and hydroxyl groups of adjacent polysaccharide molecules"). Plaintiffs simply seek a broader and vaguer construction.

While other "chemical linking" may occur between HA molecules and other molecules in the filler, the "crosslinked" HA in the asserted claims arises solely as a result of covalent bonds formed when HA and BDDE are linked.

Defendants' construction more accurately and precisely describes the claim term. It should be adopted by the Court.

Water-insoluble

Defendants' construction includes the phrase "water-insoluble" in order to describe the nature of crosslinked HA. Once again, Defendants do not understand Plaintiffs to be challenging the fact that "HA crosslinked with [BDDE]" is water-insoluble. Nevertheless, Plaintiffs, once again, would prefer a vaguer description of crosslinked HA.

The dermal fillers claimed in the '475 Patent are comprised of a combination of crosslinked and uncrosslinked HA. *See* Claims 1, 18, 27, 31, and 34. The prior art cited in the '475 Patent confirms the fact that crosslinked HA is "water-insoluble." *See, e.g.*, Cavanaugh Decl, Ex. 4,

U.S. Patent No. 8124120 B2 (referring to "crosslinked, water insoluble, hydrated hyaluronic acid gel particles" in the patent title and explaining that the crosslinked HA was water-insoluble). "[P]rior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence." *Powell v. The Home Depot, Inc.*, 663 F.3d 1221, 1231 (Fed. Cir. 2011).

The specification of the '475 Patent similarly describes crosslinked HA as being a "solid phase" of HA floating in dissolved "free HA." 7:4-9 ("The precursor composition may comprise a first component including relatively highly crosslinked HA particles in a substantially solid phase, and a second component comprising free or relatively less crosslinked HA in a substantially fluidic phase in which the relatively highly crosslinked particles are dispersed.") The crosslinked HA serves to provide the substantially solid substance that fills the facial wrinkles and depressions. *See* Cavanaugh Decl., Ex. 5 ("*Debacker*"), at 14:36-38 (describing the "injection and implantation" of crosslinked HA).

Plaintiffs have conceded for purposes of claim construction that "free HA" and "uncrosslinked HA"[3] are water soluble. *See* Section IV.A.3. They are described as such in the specification of the patents-in-suit. *See* 3:10-13 ("free HA includes truly uncrosslinked HA as well as lightly crosslinked HA chains and fragments, all in soluble form in water"). If uncrosslinked HA is defined as "water-soluble," then the crosslinked HA should be defined to reflect the undisputed fact that it is water-insoluble.

Because of the water-insoluble nature of the crosslinked HA, the patent (and the prior art) teach that it is necessary for the composition to have water-soluble free/uncrosslinked HA. These "particles" of crosslinked HA (7:33-34) need a method of conveyance, to move from the needle into the target site for filling. Free HA serves as that liquid, reducing the viscosity of the gel and facilitating injection. 7:33-35 (describing the free HA as "a carrier material"). The specification recognizes the difference between free HA and crosslinked HA when it notes that "free HA gel may be added to the HA/lidocaine gel mixture with the advantage of increasing the kinetics of lidocaine

[3] These terms are used interchangeably in the patents and in this brief.

delivery." 13:9-11. The kinetics of the composition – or the ability of the filler to move or flow – are normally impaired due to the more solid gel state of the crosslinked HA on its own. Free HA – the liquid, water-soluble portion of the composition – "increas[es] the kinetics" of delivery because it lubricates the expulsion of the otherwise solid, water-insoluble crosslinked HA.

The extrinsic evidence also shows that a person of ordinary skill in the art would understand "crosslinked HA" to refer to a water-insoluble gel. *See, e.g., Calias* at 4:45 – 5:3 (describing "a method for preparing a water insoluble biocompatible composition" with a "polyanionic polysaccharide" [such as HA] and a crosslinking agent); *Debacker* at 3:14-19 (explaining that the composition "consist[ed] of an injectable suspension whose dispersed phase consist of insoluble fragments of a hydrogel of said highly crosslinked polymer," meaning crosslinked HA), 8:1-9 (stating the macromolecular network was made of "insoluble fragments"); Cavanaugh Decl., Ex. 6 ("*Lebreton*") at [0011] (depicting a hydrogel composition as "consisting of insoluble fragments of a highly crosslinked polymer hydrogel (selected from hyaluronic acid and its salts").

Defendants' construction is supported by both the intrinsic and extrinsic evidence, as well as simple logic. It should be adopted.

Degree of Crosslinking

Defendants propose a construction that includes the limitation that the "degree of crosslinking[4]" in crosslinked HA must be between 2% and 20%. The inclusion of this limitation is necessary given the language of the patent itself and to preserve the validity of the claims.

The parties agree that the "degree of crosslinking" should be defined as "the percent weight ratio of crosslinking agent to HA monomeric units (HA disaccharide units) within the crosslinked portion of the HA based composition (i.e., (total mass of crosslinking agent / total mass of monomeric units) * 100))." Dkt. No. 52. As noted previously, the greater the amount of

[4] The parties have already agreed to the construction of "degree of crosslinking"; the only question is its inclusion as a limitation on the construction of "crosslinked HA" terms.

crosslinking agent added to a composition of HA, generally the greater the number of crosslinked HA bonds that will be produced. Measuring the amount of crosslinking agent in the crosslinked HA portion provides an indication of the stability, resilience, and flexibility of the gel.

The '475 Patent explicitly disclaimed as not within the scope of the invention any composition of crosslinked HA outside of a specified range. The specification states that "the degree of crosslinking of the present compositions is "at least about 2% and is up to about 20%" 9:31-33 (emphasis added). Use of similar phrases in the specification has been held by the Federal Circuit to be explicit disclaimers and limitations, even when it appears in the specification of a patent. *See Astrazeneca AB v. Hanmi USA, Inc.*, No. 2013-1490, 2013 U.S. App. LEXIS 25199, *8-9 (Fed. Cir. Dec. 19, 2013) (finding that the use of "the present invention" in a detailed description disclaimed other salts not listed); *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) (importing limits from specification when written descriptions referred to "this invention" or "the present invention"). "Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent." *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001).

The foregoing quote from the specification ("of the present compositions") is a description of the claimed invention and not just a preferred embodiment. This is confirmed by the specification providing several examples of narrower preferred embodiments within the defined 2-20% range of the invention. Each embodiment is explicitly within the patented range. *See, e.g.* 9:34-37 ("In some embodiments, the degree of crosslinking is between about 4% to about 12%. In some embodiments the degree of crosslinking is less than about 6%, for example, is less than about 5%.").

Accordingly, the patentee's explicit disclaimer of degrees of crosslinking outside the specified range should control. *See 3M Innovative Props. Co.*, 350 F.3d at 1374 (an explicit definition "controls the meaning of [the claim term], regardless of any potential conflict with the term's ordinary meaning ....").

Moreover, Defendants' construction is also the only way to preserve the validity of the asserted claims. *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999) (stating that, if a claim is able to be interpreted in one way that would render it invalid and one way that would keep it valid, that claim should be construed in the manner that would preserve the claim's validity). Both parties agree that for claim construction purposes "free HA" or "uncrosslinked HA" should be construed to include not just completely "uncrosslinked HA" but what the specification refers to as "lightly-crosslinked HA." Under that construction HA can be crosslinked but still be "free HA" or "uncrosslinked HA" as defined by the '475 Patent if it is only "lightly crosslinked" which, as the parties have also agreed, must be water-soluble. *See* Section IV.A.3.

Defendants' construction of crosslinked HA includes the limitation that it be water-insoluble. This provides a clear method by which one of skill in the art could distinguish between whether an HA sample is lightly crosslinked and therefore "uncrosslinked" or if it is "crosslinked" for purposes of the '475 Patent. However, as discussed on pp. 9-10, Plaintiffs oppose including the "water insoluble" limitation. But, without that limitation, there is nothing in Plaintiffs' proposed construction for crosslinked HA that defines for those of skill in the art the boundary between crosslinked and "uncrosslinked HA" or "free HA" (that includes "lightly crosslinked HA"). *See* 5:5-13 (noting that the "lightly crosslinked [HA] component of the macromolecular structure" is still Free HA).

Adoption of the Defendants' proposed limitation of a 2% - 20% degree of crosslinking in defining "crosslinked HA" provides an alternative approach. While "lightly crosslinked" is considered "free" HA in the '475 Patent, no definition is provided in the Patent as to at what point HA moves from "lightly crosslinked" HA to "crosslinked HA." Ostensibly, there must be some threshold after which HA modified with BDDE becomes "crosslinked HA." By adopting Plaintiffs' construction of "crosslinked HA," no such threshold would be identified because lightly crosslinked can qualify both as uncrosslinked HA or Free HA (as it is water soluble) and crosslinked HA because it is crosslinked (and, according to Plaintiffs' construction, not required to be water

insoluble). If Plaintiffs' construction is adopted, those of skill in the art could not be "reasonably certain" of whether, when preparing an HA dermal filler, the composition consisted of "crosslinked" or "uncrosslinked" HA because of the patentee's introduction of the concept of "lightly crosslinked HA."

Therefore, under Plaintiffs' construction, the claim would therefore be invalid as indefinite. *Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 13-369, 572 U.S. __, slip op. at 9 (2014). In contrast, Defendants' construction preserves the validity of the asserted claims by providing a clear delineation of what is "crosslinked HA" versus what is "free HA" or "uncrosslinked HA" by providing that boundary between what level of crosslinking would only be considered "lightly crosslinked" and what would be considered truly "crosslinked". The 2% limitation provides the necessary threshold. A composition of HA with less than 2% degree of crosslinking would be "lightly crosslinked."

For the above reasons, the Court should adopt Defendants' proposed construction for the "crosslinked HA" terms.

3. Claims 1, 2, 4, 9, 18, 31, 33, 34, and 36: "uncrosslinked HA" / Claims 19, 27, 28, and 29: "free HA"

Claim term	Plaintiffs' construction	Defendants' construction
uncrosslinked HA / free HA	Water-soluble HA (i.e. uncrosslinked HA and/or lightly crosslinked HA)	Water-soluble HA (i.e. uncrosslinked HA and/or lightly crosslinked HA) that is added to the crosslinked HA portion of the composition

The above claims use either the term "uncrosslinked HA" or "free HA." As noted previously, the parties have agreed these terms should be construed the same way. Dkt. No. 52.

Defendants propose that "free HA" and "uncrosslinked HA" be construed to be only the free HA that is added to the composition after the crosslinking process to create crosslinked HA has been completed. This construction is based on disclaimers to overcome the prior art made by the

patentees in the prosecution of the '475 Patent. This is also consistent with the specification's description of the invention.

As described previously, the prior art taught the ability after the crosslinking process to add uncrosslinked HA to an HA dermal filler composition to improve the injectability of the filler. The specification of the '475 Patent itself describes the addition of free HA to an already-crosslinked mass of HA. 7:33-35 ("These particles are then mixed with a carrier material, for example, an amount of free HA to produce a gel."); 13:13-15 ("This free HA gel is then added to the crosslinked HA/lidocaine gel."). Similarly, prior art patents describe adding free HA to crosslinked HA in a dermal filler to improve certain properties. *See, e.g., Reinmuller II*, 5:6-13.

To overcome a rejection of the claims by the Examiner during prosecution of the '475 Patent, Plaintiffs disclaimed a composition in which free HA is not added after crosslinking occurs. Statements during prosecution of an application "'limit[] the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.'" *Springs Windows Fashions v. Novo Indus., Inc.*, 323 F.3d 989, 994 (Fed. Cir. 2003) (citation omitted); *see also Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323-24 (Fed. Cir. 2003) ("The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution."); *Chimie v. PPG Industries Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history is to 'exclude any interpretation that was disclaimed during prosecution.'").

The Patent Examiner originally rejected the patentee's claim for "crosslinked HA containing an anesthetic and greater than about 10% uncrosslinked HA." Cavanaugh Decl., Ex. 7, Nov. 9, 2011 Response to Office Action at p. 11. The Examiner relied on Lebreton (U.S. Patent App. 2006/0194758), which disclosed a preferred embodiment comprised of 6.5% crosslinked HA. *Id.* The Examiner concluded that the remaining HA, or 93.5%, in Lebreton must necessarily be uncrosslinked and greater than the 10% uncrosslinked HA the patentees had claimed. *Id.*

The patentees countered that the Examiner had misunderstood Lebreton, and that with 6.5% crosslinking "there is no reason to believe that Lebreton's compositions would have any uncrosslinked HA." *Id.* at p. 12. As the patentees told the Examiner, the reason for this is that crosslinking of HA occurs at select locations on the HA and BDDE molecules. It is the reactivity of the molecules – their likelihood of forming covalent bonds at these locations – that forms the crosslinked network. The patentees advised the USPTO that the HA in Lebreton had 3,855 possible crosslinking locations. *Id.* at 11. According to the patentees, adding 6.5% of crosslinking agents would mean that each HA molecule would be crosslinked at 250 locations on average. *Id.* at 11. As a result, according to the patentees, there would be an "infinitesimally small" chance that any of the HA molecules would fail to have at least some crosslinking. *Id.* at pp. 11-12. In response to this argument, the Examiner withdrew the rejection. Cavanaugh Decl., Ex. 8, Jan. 30, 2012 Office Action at p. 5.

In other words, according to the patentees, in the prior art Lebreton, when free HA (as the term “free HA” or “uncrosslinked HA” is used in the ‘475 Patent) is put through a crosslinking process with 6.5% crosslinking agent, no "free HA" or "uncrosslinked HA" continues to exist. Following the same logic, even with 2% crosslinking agent, the lowest degree of crosslinking according to the specification, each HA molecule would still be crosslinked at 77 locations on average, thus still no “free HA” or “uncrosslinked HA.” For a composition to be comprised of both "crosslinked" and "uncrosslinked" HA, then, that uncrosslinked HA *must* be added after the reaction has completed. Therefore, the patentees disclaimed any composition in which free HA is not added after the crosslinking process.

The Patentees and the Examiner confirmed this understanding in subsequent communications. In a Jan. 30, 2012 Office Action, the Examiner, looking at the same Lebreton application in combination with the Reinmuller patent, U.S. Patent No. 7,902,171 B2[5] noted that the Reinmuller patent taught "admixing uncross-linked hyaluronic acid to the preparations of

[5] This was the English equivalent of PCT WO 2005/067944.

exclusively cross-linked hyaluronic acid." *Id.* at p. 7.[6] The examiner therefore found the claims obvious. *Id.* at 8.

Given the patentees' prior argument that the crosslinking process would leave no "free HA" or "uncrosslinked HA" and they were only claiming adding the "free HA" or "uncrosslinked HA" later, the Examiner rejected the claim based on Reinmuller's teaching of doing precisely that. *Id.*

In a July 30, 2012 response, the patentees did not challenge that Reinmuller taught "admixing" uncrosslinked HA to a crosslinked HA composition or that their claims sought to cover HA that might remain uncrosslinked notwithstanding the crosslinking process. Instead, the patentees distinguished Reinmuller on the grounds that it did not teach adding the proper *percentage* of uncrosslinked HA "in a preparations [*sic*] comprising admixed crosslinked and uncrosslinked hyaluronic acid." Cavanaugh Decl., Ex. 9, July 30, 2012 Office Action at p. 11. The patentees argued that the claimed invention was nonobvious because one of ordinary skill "would have recognized that *adding uncrosslinked HA to a crosslinked HA composition* would affect the viscoelastic properties of the composition … Thus if a person were to *add uncrosslinked HA to a crosslinked HA composition*, only a small or minor amount of uncrosslinked HA, and certainly less than 10% by volume, would be added …" *Id.* at 12 (emphasis added). In other words, Reinmuller did not teach the benefits of adding a large amount of free HA after the crosslinking process was completed, while the patentees did.

The Examiner confirmed this understanding of the patentees' arguments in a Nov. 19, 2012 Office Action, stating "[t]he Applicant argues that the prior art does not teach adding the uncrosslinked HA to the composition in an amount of at least 10% …". Cavanaugh Decl., Ex. 10, Nov. 19, 2012 Office Action at p. 6.

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[6] Reinmuller identified a complication experienced by patients using HA dermal fillers – inflammatory side effects at the injection site. *Reinmuller II* at 5:6-8. Reinmuller proposed a solution – "[t]hese side effects can be suppressed according to the invention by admixing noncrosslinked hyaluronic acid [*i.e.*, "free HA" or "uncrosslinked HA"] to the preparations of exclusively crosslinked hyaluronic acid." *Id.* at 5:10-13.

Having represented to the Examiner during prosecution that the claim terms "free HA" and "uncrosslinked HA" refer to uncrosslinked HA *added* to the composition (in an attempt to overcome rejections based on the prior art and secure a patent), Plaintiffs cannot now expand the scope of their claimed subject matter to include what they had disclaimed previously – "free HA" or uncrosslinked HA that might still exist after the crosslinking process without any subsequent adding of free HA. Defendants, along with the rest of the public, are entitled to rely on Plaintiffs' definitive statements to the USPTO in forming their understanding of the scope of the claims in the issued patent. *See Omega Eng'g*, 334 F.3d at 1324 ("As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution.") To allow otherwise would undermine the public notice function of patents.

Defendants' construction should be adopted in its entirety.

B. Claim Construction for the '795 Patent

1. Claim 1: "hyaluronic acid (HA) component crosslinked with a crosslinking agent"

Claim term	Plaintiffs' construction	Defendants' construction
Hyaluronic acid (HA) component crosslinked with a crosslinking agent	HA that forms a macromolecular structure resulting from chemical linking of HA by a crosslinking agent	HA that has been covalently modified with a crosslinking agent to form a macromolecular structure that is water-insoluble, such that the degree of crosslinking is at least about 2% and is up to about 20%. "Degree of crosslinking" as used herein has the same construction as agreed by the parties within the '475 Patent.

The claim term above differs from the construction for the "crosslinked HA" terms in the '475 Patent only in the crosslinking agent; the '475 Patent is limited to BDDE, while the '795 Patent contains no such restriction and includes all crosslinking agents.

As with the '475 Patent, both parties accept that HA and a crosslinker form a macromolecular structure. However, the three same disputes identified in the '475 patent remain ("Covalently modified," "water-soluble" and "degree of crosslinking").

Covalently Modified

The support for including these terms in the construction can be found in Section IV.A.2, *supra*.

Water-insoluble

As with the '475 Patent, the inventor defined free HA and uncrosslinked HA to be water-soluble. *See* 3:10-13 ("free HA includes truly free HA as well as lightly crosslinked HA chains and fragments, all in soluble form in water"). The support for construing crosslinked HA to be water-insoluble can be found in Section IV.A.2, *supra*.

Degree of Crosslinking

As with the '475 Patent, the '795 Patent explicitly defines the patented composition to be limited to a degree of crosslinking range of 2% - 20%. The inventor clearly indicates that all "present compositions" fall within the degree of crosslinking range between "at least about 2%" and "up to about 20%." 10:22-24. As described in Section IV.A.3, *supra*, both parties agree that free/uncrosslinked HA includes "lightly-crosslinked HA."

As with the '475 Patent, without including the "degree of crosslinking" in the "crosslinked HA" definition, this "lightly-crosslinked" HA could erroneously be considered part of the defined crosslinked HA because Plaintiff provides no basis on which to distinguish the two.

IV. CONCLUSION

This Court should adopt Defendants' proposed constructions.

Dated: June 13, 2014

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